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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,330	01/23/2004	Michael P. Cooke	P1097US10	5772

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
01/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/764,330	COOKE ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/22/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14-16,28-32 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14,15,28-32 and 39-41* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 10/22/08, are acknowledged.

Claims 12, 14, 30, and 32 have been amended.
Claims 39-41 have been added.
Claims 12, 14-16, 28-32, and 39-41 are pending and are under examination.

2. The rejections of the claims under 35 U.S.C. 112 first and second paragraphs are withdrawn in view of Applicant's amendment to the claims.

3. The following are new grounds of objection and rejection.

4. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 28-29 are objected to because of the following informalities: The claims recite that the IP3KB has "an" amino acid sequence or "a" nucleotide sequence of SEQ ID NO: 1, 2, 3, or 4. However, the recitation of "an" amino acid sequence does not clearly indicate that the IP3KB has the entire sequence of the SEQ ID No.(for example, "an" amino acid sequence might encompass 3 amino acids of SEQ ID NO: 1). The claims should be amended to recite "the" amino acid sequence of SEQ ID NO: 1 or "the" nucleotide sequence of SEQ ID NOs: 2-4. Appropriate correction is required.

6. The amino acid sequences of Accession Nos. CAB65055, CAC40660, and NP_002212 are essential to practice the claimed invention. The specification on page 31 states that all GenBank sequences are incorporated by reference. However, the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

If applicant adds the sequence, Applicant should also comply with the sequence requirements 37 CFR 1.821-1.825.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite in the recitation of an amino acid sequence of Accession No. CAB65055, CAC40660, and NP_002212. The use of an Accession number as the only means to identify the claimed amino acids sequences renders the claim indefinite, since the data in an Accession No. is not static, but may be modified over time.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14-15, 28-32, and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for identifying an agent that inhibits T lymphocyte development comprising identifying an agent that inhibits IP3KB kinase activity or gene/polypeptide expression and testing the agent for the ability to inhibit CD4+CD8+ T cell double positive T cell development into CD4+ or CD8+ T cells, does not reasonably provide enablement for:

A method for identifying an agent that inhibits T lymphocyte development comprising identifying an agent that inhibits IP3KB kinase activity or gene/polypeptide expression and testing the agent for the ability to inhibit T lymphocyte development at the double positive stage.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the

claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)" The MPEP further states that physiological activity can be considered inherently unpredictable.

The instant claims are drawn to a method of identifying an agent that inhibits T lymphocyte development comprising identifying an agent that inhibits IP3KB kinase activity or gene/polypeptide expression, and testing said agent for the ability to inhibit T lymphocyte development at the double positive stage. T cell development comprises a series of distinct phases of differentiation marked by changes in receptor expression. Progenitor cells in the thymus first past through a double negative stage of differentiation. Said double negative thymocytes then further differentiate into CD4 and CD8 expressing double positive cells, followed by maturation into CD4 or CD8 single positive T cells (see Janeway and Travers, pages 6:6-6:7). The instant claims recite that the agents are tested for their ability to inhibit T lymphocyte development "at the double positive stage". This might reasonably encompass inhibition such that no double positive cells are formed, or inhibition such that double positive cells are generated, but are blocked from further maturation into CD4 or CD8 single positive T cells. The instant specification demonstrates that inhibition of IP3KB results in a block in T development, such that double positive CD4+CD8+ cells are generated, but mature

single positive T cells are not obtained. Therefore, the instant specification enables a method of identifying an IP3KB inhibitory agent that inhibits T cell development comprising testing an agent for the ability to inhibit double positive T cell development into CD4 or CD8 single positive T cells. However, claim 12 encompasses testing the ability of the agents to inhibit the formation of double positive cells (i.e. inhibit T lymphocyte development "at the double positive stage"). However, since IP3KB inhibition does not influence the generation of double positive cells, the method would not result in the identification of an agent that can inhibit T cell development as broadly claimed. Accordingly, the method as broadly claimed must be considered highly unpredictable. Given said unpredictability, the method of the instant claims must be considered to require undue experimentation.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes

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